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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/138,735	08/24/1998	GLAUCIA PARANHOS-BACCALA	WPB-36400B	4465

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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/138,735

Applicant(s)

Baccala et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 21, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 7, 8, 10-27, 32, 34, and 36-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 5, 7, 8, 10-27, 32, 34, and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Applicant's amendment filed June 21, 2002 (Paper Number 22) has been received and entered. Consequently claims 1, 2, 5, 7, 8, 10-27, 32, 34, and 36-40 remain pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

2. The rejection of claims 5, 7, 8, 11-20, 25, 26, 32, 34, and 36-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such[^] a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

3. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

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as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicant's are asserting that it would be within the skill of the art to use fragments having at least 85% homology to a reference sequence as a probe or primer. Applicant's further assert that one of ordinary skill in the art would understand that a fragment having 85% homology to the reference sequence can be successfully hybridized to the reference sequence.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of Applicant's claim language. For instance, each of the recited claims functions as a probe and/or primer. However, each of these sequences are enabled only for "consisting of" the recited sequence. The claim language currently allows for an unspecified number of nucleotides upstream and/or downstream of undefined structure. Each of these additional nucleotides will have a profound impact on the function of the primer and/or probe. Without guidance as to which upstream and downstream nucleotides are necessary for functioning as a successful primer or probe, one of skill in the art would be forced into undue experimentation to determine which upstream and downstream nucleotides effect the probes performance.

Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

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4. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicant's are asserting that unlike Eli Lilly, the present specification provides a precise definition of the claimed nucleic acid in a manner that is sufficient to distinguish the claimed nucleic acids from other nucleic acids. Applicant's further assert that the claimed nucleic acids are identified by distinguishing structural characteristics.

Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be fully persuasive in view of the claim language.

First, the claims are open ended, i.e., "comprising." It is this language which is not sufficiently described in the specification to allow those of skill to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims merely recite percent identity to a fragment of a nucleotide sequence without any associated activity. Applicant's solely described activity for the described fragments is that of a probe or primer. However each of these uses is dependent upon the precise structure being used. Substitutions upstream or downstream of the recited fragment will have a profound effect upon the activity of the primer or probe. Consequently, the written description of the claimed fragments is only described sufficiently to enable "consisting of" language.

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Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 5, 8, 10-11, 17, 25-26, 32, 34, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Birkett *et al.*

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The claims are drawn to isolated probe which is identical or fully complementary to nucleotides 1232-2207 of SEQ ID NO: 1; wherein said probe contains at least 5 and no more than 100 nucleotides.

Birkett *et al* (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that the isolated hexamer oligonucleotide primers contain every possible nucleotide sequence of six consecutive nucleotides, and that these sequences will inherently match those of SEQ ID NO: 1, the disclosure of the hexamer kit by Birkett *et al* is seen to anticipate the claimed invention.

Claims 1-2 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

September 9, 2002